Attorney Docket No: SAI-004.01

STENT HAVING INFLATABLE LINING

~~Lined Balloon Mounted Stent (detailed description) :~~

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is the national stage of International application no. PCT/EG2003/000009, filed Nov. 22, 2003, which claims the benefit of Egyptian application no. EG2003090947, filed Sep. 24, 2003.

BACKGROUND

[0002] To achieve control over the blood flow inside blood vessels a surgical procedure is undertaken to band the vessel from outside. The band compresses the vessel and thereby decreases the diameter of its lumen. Different systems had been devised for this but they were all applied from outside the vessel. Costs, risks, and limitations inherent to such surgical banding procedures include:

[0003] High cost of the surgery, with inherent risks and problems associated with the throracic surgeries.

[0004] Sometimes the condition of the patient (e. g. a sick baby) is not suitable for the operation despite its urgency.

[0005] The inability to change the degree of the band once the operation is over except with another operation with again higher risks.

[0006] Fibrosis and distortion produced during and after the surgery would make future operations in the area involved more difficult.

SUMMARY

[0007] ~~This invention is about to mount a~~A ~~non~~ non-reactive inflatable tissue (or "lining") may be mounted on an appropriate size intravascular stent to control the flow distally when the stent is positioned in a blood vessel. The stent is fixed to the vessel, and the lining may be inflated or deflated inwardly from the stent to control the portion of

the vessel lumen available for flow in the stented region. This ~~created~~ stent is ~~then~~ placed ~~on~~ in the intended vessel ~~per~~ by catheter. This tissue or lining can be ~~put~~ formed in ~~different~~ various designs:

[0008] 1. A tire (the lining) in a wheel (the stent) with a central opening (the artificial lumen).

[0009] 2. In the form of successive ~~openings~~ narrowings (artificial lumens) of different sizes to allow for future change in the size of the stenosis imposed to the circulation by interventions e.g. balloon catheters to remove one of the narrowings for example.

[0010] 3. Crescentic or boggy (spongy) masses of enclosed tissue that can be compressed later on e.g. by a balloon to modify the gradient across the stenosis produced e.g. pulmonary artery.

[0011] 4. A design similar to naturally occurring stenotic valves.

[0012] 5. A stenotic absorbable material to allow for natural progressive dilatation.

[0013] 6. A stenotic material that swells with time to allow for progressive narrowing.

BRIEF DESCRIPTION OF DRAWINGS

[0014] ~~Figure~~ FIGS. 1A and 1B show, respectively, longitudinal- and transverse cross-sections of a device 10 having an annular inflatable lining 20 mounted inside a cylindrical stent 30.

[0015] FIG. ~~and~~ 2 ~~demonstrate a sketch of one version of items 1 and 4~~shows a longitudinal cross-section of a device 40 having an inflatable lining 50 that mimics a naturally-occurring stenotic valve, mounted inside a cylindrical stent 30.

DETAILED DESCRIPTION

[0016] Many of the costs and risks of banding surgery can be avoided by controlling the lumen of a blood vessel intravascularly than extravascularly. To do so, a typical vascular stent is augmented with an inflatable lining on its inner aspect. When the lining is

inflated, it expands inwardly, thereby partially occluding the vessel. Unlike typical stents, which are used to enlarge vessel narrowings, the present inflatable-lining stent is intended to narrow a vessel. Such lumen narrowing may be desirable to control excessive flow in a vessel, such as excessive pulmonary artery blood flow in a sick baby.

[0017] The procedure of pulmonary artery banding and related procedures has never been reported in the literature as having been done intravascularly.

[0018] All the~~se~~ designs disclosed herein can be inflated or deflated to control their size during the procedure and sometimes later as well. The inflation can be done by carbon dioxide, air or even different fluids e.g. normal saline. The addition of the ability to compress the narrowed segment later on by dilating balloons is ~~again~~ feasible as well.

[0019] This could replace state of the art procedures e. g. the pulmonary artery band that we know and are using now.

[0020] For this purpose ~~the~~ metallic dilatable stents in common use in cardiology practice can be prepared to hold the balloon inside it. The balloon material that can be used is similar to the one used in valvotomy balloons in our current practice, however the essential requirements are~~is~~ only inflatability and non reactivity.

[0021] As this procedure is expected to be done in the catheterization laboratory, I believe it would be executed with much less mortality, morbidity and expense as compared to its surgical counterpart. I expect it thus to revolutionize the practice. Because the ability to perform a per catheter band without mortality will definitely make surgical corrections of some simple, as well complicated, cardiac lesions not needed or at least deferrable to the time where they could be done with less mortality. If we combine this by the ability to control the pressure gradient during insertion (e. g. doing echo or direct measurement in the cath and ascertaining the hemodynamic consequences directly). Again, the ability to reduce or increase the pressure gradient at the same setting or at later settings. For more complex lesions, it can be done as a permanent palliation or in preparation for future palliation.

[0022] Benefits of the disclosed devices and methods include:

~~I suggest the name of Lotfy's stent for the stent that will be designed for this purpose.~~
~~The previous state of the art:~~

~~To achieve control over the blood flow inside the vessels a surgical procedure is undertaken (with its inherent costs, risks) to band the vessel from outside. Different systems had been devised for this but they were all applied from outside the vessel.~~
~~Problems in the previous state of the art:~~

~~1. High cost of the surgery, with inherent risks and problems associated with the throracic surgeries.~~
~~2. Sometimes the condition of the patient (e. g. a sick baby) is not suitable for the operation despite its urgency.~~
~~3. The inability to change the degree of the band once the operation is over except with another operation with again higher risks.~~
~~4. Fibrosis and distortion produced during and after the surgery would make future operations in the area involved more difficult.~~
~~What is new about the invention?~~

[0023] 1. Achievinge the same result as ~~the~~ a surgical intervention.

[0024] 2. Avoiding the risk and complications of surgery and reoperation.

[0025] 3. Providing ~~T~~the ability to change the degree of narrowing produced during and after the catheter procedure.

~~The procedure of pulmonary artery banding and related procedures was never reported in the literature to be done intravascularly.~~

~~How can it be used?~~

~~A selected company producing the common use intravascular stent will be chosen after agreement with the inventor to upgrade some of its stents with the new designs and linings I suggested.~~